UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ENDO PHARMACEUTICALS INC. and GRÜNENTHAL GMBH, Plaintiffs, v. AMNEAL PHARMACEUTICALS, LLC AND AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, Defendants.	C.A. No. 12-cv-8115-TPG
ENDO PHARMACEUTICALS INC., Plaintiff, v. RANBAXY LABORATORIES LTD., RANBAXY INC., and RANBAXY PHARMACEUTICALS INC., Defendants.	C.A. No. 13-cv-8597-TPG
ENDO PHARMACEUTICALS INC., Plaintiff, v. ACTAVIS INC. and ACTAVIS SOUTH ATLANTIC LLC, Defendants.	C.A. No. 12-cv-8985-TPG

ENDO PHARMACEUTICALS INC., Plaintiff, v. PAR PHARMACEUTICAL COMPANIES, INC. and PAR PHARMACEUTICAL, INC. Defendants.	C.A. No. 13-cv-3284-TPG
ENDO PHARMACEUTICALS INC., Plaintiff, v. ROXANE LABORATORIES, INC., Defendant.	C.A. No. 13-cv-3288-TPG
ENDO PHARMACEUTICALS INC., Plaintiff, v. RANBAXY LABORATORIES LTD., RANBAXY INC., and RANBAXY PHARMACEUTICALS INC., Defendants.	C.A. No. 13-cv-4343-TPG

PLAINTIFF'S STATEMENT OF THE ELEMENTS AND FACTS CONCERNING ITS CLAIMS FOR PATENT INFRINGEMENT

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I. SUMMARY OF THE ACTION AND THE PARTIES

1. This is series of eleven related Hatch-Waxman Act patent infringement lawsuits that Plaintiff Endo Pharmaceuticals Inc. ("Endo"), and in some cases along with co-Plaintiff Grünenthal GMBH ("Grünenthal"), filed in this District against generic companies that have filed Abbreviated New Drug Applications ("ANDAs") seeking FDA approval to sell generic versions of to Endo's Opana® ER tablets.[1]

2. These actions arise under the Hatch-Waxman Act, 21 U.S.C. § 355(j), which provides for the orderly determination of patent infringement claims prior to the introduction of generic pharmaceutical products into the market. In short, the FDA approves New Drug Applications ("NDAs") filed by companies like Endo and Grünenthal which meet the stringent requirements to obtain permission to sell a new pharmaceutical product. Generic companies, like the Defendants, can take a shortcut through the approval process by filing an ANDA seeking to make a copy of the NDA-holder's product, thereby avoiding the need for costly studies and development work.

3. The right to file an ANDA comes with an obligation to respect the patent rights of the NDA holder. The FDA keeps a list of patents applicable to each NDA in what is known as the "Orange Book". The filing of an ANDA triggers notice to the NDA holder and provides the jurisdictional basis to commence suit for patent infringement before the generic product is

[1] Endo has sold two versions of Opana® ER—the original ("non-CRF") formulation launched in 2006, as well as a subsequent crush-resistant formulation ("CRF") designed to deter potential abuse by drug abusers seeking to crush and then snort the tablets. The active ingredient in both versions of Opana® ER is the same—namely, oxymorphone hydrochloride. Defendants Roxane (13-cv-3288), Ranbaxy (13-cv-4343), Actavis (12-cv-8985), and Par (13-cv-3284) seek to market a generic version of the original formulation of Opana® ER and Defendants Amneal (12-cv-8115), Actavis (13-cv-436), Impax (13-cv-435), Sandoz (12-cv-8318), ThoRx (12-cv-8317), Teva (12-cv-8060), and Ranbaxy (13-cv-8597) seek to market a generic version of the CRF version of Opana® ER. The above-captioned cases are those where only Endo's patents are currently asserted. These cases will be tried together with the cases where both Endo and Grünenthal patents are asserted.

approved. If the generic product infringes a patent, the generic can still obtain approval, but will merely be required to delay its product launch until after expiration of the NDA holder's patents.

4. Endo is the holder of NDA 201655 for crush-resistant, controlled release oxymorphone tablets, which it sells under the name Opana® ER and which have been referred to in these suits as Opana® ER CRF. The active ingredient, oxymorphone, is a powerful narcotic used to treat severe pain and is a Schedule II Controlled Substance, which must be manufactured and distributed under controlled conditions. Endo brought the original version of the product to market in 2006 (FDA approved under NDA 21-610), and then in collaboration with Grünenthal, launched a crush-resistant formulation to deter drug abuse in 2012.

5. Each of the Defendants filed ANDAs with the FDA seeking approval to make a generic version of Opana ER®.[2] Such conduct constitutes infringement under 35 U.S.C. § 271(e)(2) of two or more of Plaintiffs' patents that are listed in the FDA's "Orange Book" as covering Opana® ER. Moreover, if the FDA approves Defendants' ANDAs and Defendants offer their generic tablets for sale, Defendants would thereby infringe one or more of the same patents under 35 U.S.C. § 271(a), (b), and (c). Defendant Actavis is already selling generic Opana® ER tablets pursuant to one of the two ANDAs it has filed (the other is still pending before FDA), and therefore it is already infringing Endo's patents under 35 U.S.C. § 271(a), (b), and (c) with respect to those tablets.

6. The four patents asserted against some or all of the Defendants are Endo's United States Patent Nos. 8,309,122 ("the '122 patent"), 8,329,216 ("the '216 patent"), and Grünenthal's United States Patent Nos. 8,114,383 ("the '383 patent"), and 8,309,060 ("the '060

[2] Defendants Actavis and Ranbaxy have each filed two ANDAs, one with respect to the original formulation of Opana® ER and the other with respect to the CRF version of Opana® ER. Hence, there are two lawsuits against each of those Defendants.

patent"). The following table indicates which Defendants Plaintiffs accuse of infringing which patents:

CASE NO.	PRINCIPAL DEFENDANT	PATENTS-IN-SUIT
12-cv-8060	Teva Pharmaceuticals USA, Inc.	'122, '216, '383, '060
12-cv-8115	Amneal Pharmaceuticals, LLC	'122, '216
12-cv-8317	ThoRx Laboratories, Inc.	'122, '216, '383, '060
12-cv-8318	Sandoz Inc.	'122, '216, '383, '060
12-cv-8985	Actavis Inc. (ANDA No. 79046)	'122, '216
13-cv-435	Impax Laboratories, Inc.	'122, '216, '383, '060
13-cv-436	Actavis Inc. (ANDA No. 203930)	'122, '216, '383, '060
13-cv-3284	Par Pharmaceutical Companies, Inc.	'122, '216
13-cv-3288	Roxane Laboratories, Inc.	'122, '216
13-cv-4343	Ranbaxy Laboratories Ltd. (ANDA No. 203506)	'122, '216
13-cv-8597	Ranbaxy Laboratories Ltd. (ANDA No. 204527)	'122, '216

II. EXPECTED WITNESSES

7. Plaintiffs anticipate that they may call the following witnesses[3] during the course of the trial, either during their own case-in-chief or in rebuttal to the defenses that Defendants may raise, and the subject matter about which Plaintiffs anticipate they will testify if called as a witness is, broadly speaking, as follows:

[3] Some witnesses listed below will present testimony that is only relevant to the following cases where Grünenthal's patents are asserted: *Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.*, 12-cv-8060; *Endo Pharmaceuticals Inc. v. Impax Laboratories, Inc.*, 12-cv-8317; *Endo Pharmaceuticals Inc. v. Impax Laboratories, Inc.*, 13-cv-435; *Endo Pharmaceuticals Inc. v. Actavis Inc.*, 13-cv-436; *Endo Pharmaceuticals Inc. v. Sandoz Inc.*, 12-cv-8318.

(1) Anand Baichwal, Former Senior Vice President of Licensing and Chief Science Officer at Penwest Pharmaceuticals[4], a co-inventor of the '122 and '216 patents, will testify regarding the conception and development of the inventions claimed in the '122 and '216 patents.

(2) Dr. Johannes Bartholomäus, the head of Grünenthal's Pharmaceutical Development Department from 1992-2008, a co-inventor on the '383 and '060 patents, will testify regarding making of the Grünenthal inventions of the asserted claims of the '383 and '060 patents.

(3) Gregory Bell, Vice President at Charles River Associates and an expert in business economics, will testify regarding the commercial success of Opana® ER.

(4) Steven Cowan, Vice President of External Supply Qualitest at Endo, will testify regarding Endo's [redacted]

(5) Dr. Stanley Davis is an expert in the development and evaluation of pharmaceutical delivery systems, including oral controlled-release formulations with polymeric excipients. Dr. Davis will present expert evidence that Defendants' Tablets infringe the asserted claims of the '383 and '060 patents, including evidence regarding how terms of the '383 and '060 patent claims should be construed as well as how Defendants' Tablets meet each and every limitation of the asserted claims. Dr. Davis may also return in Plaintiffs' rebuttal case to respond to Defendants' expected non-infringement and invalidity arguments.

(6) Dr. Reza Fassihi, an expert in biopharmaceutics, pharmacology, pharmaceutical dosage form development, and industrial pharmacy, will testify regarding Defendants' infringement of the '122 and '216 patents, and the failure of Defendants to prove invalidity of the '122 and '216 patents by clear and convincing evidence.

(7) Ivan Gergel, former Chief Science Officer at Endo, will testify regarding the development and testing of Opana® ER.

(8) Dr. Robert N. Jamison, an expert in pain management and abuse issues associated with opioids, will provide expert evidence relating to opioids, opioid abuse, and its history, as well as the need for abuse-deterrent technologies. Dr. Jamison may respond to Defendants' arguments regarding the state of the art relating to abuse-deterrent technology at the time of the Grünenthal inventions.

(9) Dr. Alexander Kraus, Vice President of Product Development and Technical & Government Affairs at Grünenthal, will testify about the commercial significance of the Grünenthal patents, including Grünenthal's extensive licensing of the '383 and '060 technology.

[redacted]

(10) Dr. David Lee, former Endo Chief Scientific Officer, a co-inventor of the '122 and '216 patents, will testify about the conception and development of the inventions claimed in the '122 and '216 patents, the development of Opana® ER, and the need for and importance of Opana® ER.

(11) Brian Lortie, Senior Vice-President of Branded Pharmaceuticals at Endo, will testify regarding the need for, and importance and commercial success of Opana® ER.

(12) Ann Maloney, former employee of Roxane Laboratories and inventor of the WO 01 08661 patent publication, upon which Defendants rely as alleged prior art, will testify by deposition regarding prior art and the state of the art at the time of the inventions claimed by the '122 and '216 patents.

(13) Dr. Stephan Ogenstad, an expert in biostatistics, will testify regarding Defendants' infringement of the '122 and '216 patents, and Defendants' failure to prove invalidity of the '122 and '216 patents by clear and convincing evidence.

(14) Plaintiffs may also call Dr. Chris Rauwendaal, an expert in extrusion, in the rebuttal case to testify about principles of hot-melt extrusion process as well as Defendants' alleged replication of the McGinity Application.

(15) Dr. Edgar Ross, a board-certified anesthesiologist and expert in pain management, will testify about the use of long-acting opioids, the need and importance of the claimed invention, the pharmacoeconomics of the opioid market, and the need for clinical trials and analysis to determine whether a new drug is safe and effective for its intended purpose. Dr. Ross will also testify about the problems with opioid abuse, the various approaches to try to solve the problem, and the observed impact of crush-resistance opioid formulations.

(16) Dr. Salomon Stavchansky, an expert in biopharmaceutics, pharmacokinetics, and pharmacodynamics, will testify regarding the non-obviousness of the '122 and '216 patents in light of the prior art cited by Defendants.

8. In addition, Plaintiffs may call other witnesses disclosed to Defendants in their February 25, 2015 witness list, including (1) Defendants' deposition witnesses who testified regarding Defendants' ANDAs and Defendants' infringement of the patents-in-suit, and (2) other

Endo and/or Grünenthal employees whose testimony may rebut arguments Defendants may make at trial. [5]

III. LEGAL STANDARDS

A. Infringement

9. Determining infringement is a two step process. "First, the court determines the scope and meaning of the patent claims asserted, and then the properly construed claims are compared to the allegedly infringing device." *Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370, 1375 (Fed. Cir. 2006) (internal quotation marks omitted).

i. Claim Construction

10. The claims are construed from the perspective of a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). Determining the meaning of claim terms requires "read[ing] the words used in the patent documents with an understanding of their meaning in the field, and . . . knowledge of any special meaning and usage in the field." *Id.* Claim terms "must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology." *Id.* Further, under the doctrine of claim differentiation, dependent claims are presumed to be of narrower scope than the independent claims from which they depend. *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1242 (Fed. Cir. 2003).

11. In determining the meaning of a claim term, a court may look to intrinsic evidence, including the claim language, specification, and prosecution history, as well as extrinsic evidence. *See Phillips*, 415 F.3d at 1312-19. In reviewing this evidence, the Federal Circuit has "long emphasized the importance of the specification in claim construction." *Id.* at

[5] This discussion is not intended to indicate the order of Plaintiffs' witness presentation or to limit the subject matter a witness may address. Not all witnesses whose testimony may be offered by deposition have been listed.

1315. It is "the single best guide to the meaning of a disputed term" and is usually "dispositive." *Id.* (citation omitted). In particular, where the specification reveals "a special definition given to a claim term by the patentee," the "inventor's lexicography governs." *Id.* at 1316. It is improper, however, to limit the claims to specific embodiments set forth in the specification. *Id.* at 1323.

12. When construing patent claims, "[i]n addition to consulting the specification," a court "should also consider the patent's prosecution history, if it is in evidence." *Id.* at 1317 (citation omitted). The Federal Circuit has recognized, however, that "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.* Where a party alleges that the inventors limited their claims by making statements in the prosecution history, it must show that "the allegedly disclaiming statements constitute 'a clear and unmistakable surrender of subject matter.'" *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1342 (Fed. Cir. 2009) (citation omitted).

13. A court may also consider extrinsic evidence, which includes "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317 (citation omitted). However, "while extrinsic evidence 'can shed useful light on the relevant art,'" it is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Id.* (citations omitted).

14. The Federal Circuit has noted that during claim construction, "expert testimony can be useful" to "provide background on the technology at issue" and "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning

in the pertinent field." *Id.* at 1318. In order to assist the court in construing the disputed claim terms, Plaintiffs therefore will offer expert testimony on the construction of the disputed terms at trial.

ii. Direct Infringement

15. To prove direct infringement, Plaintiffs must prove by a preponderance of the evidence that, if Defendants' ANDAs are approved, the manufacture, use, or sale of their generic tablets would meet each and every element of the claims. *Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1278 (Fed. Cir. 2013). Infringement is proved by comparing the asserted claims, as construed, to the accused product. *Baxter Healthcare Corp. v. Spectramed, Inc.*, 49 F.3d 1575, 1582 (Fed. Cir. 1995). Where the act of infringement was the filing of an ANDA application, the comparison is made between the patent claims and the product that is likely to be sold following FDA approval. *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002). Because drug manufacturers are required to sell products that comport with the ANDA's description of the drug, an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry. *Id.*

16. If Defendants' tablets do not literally meet an element of the claims as written, those tablets will still infringe under the doctrine of equivalents if any differences between the element that is not literally met and a corresponding element in the accused tablet are insubstantial. *Pozen Inc. v. Par Pharm., Inc.*, 696 F.3d 1151, 1167 (Fed. Cir. 2012). Differences are insubstantial if "the accused product[] perform[s] substantially the same function in substantially the same way with substantially the same result as each claim limitation in the patented product." *Id.* One way of proving infringement under the doctrine of equivalents is by showing on a limitation by limitation basis that the accused product performs substantially the

same function, in substantially the same way, to achieve substantially the same result as each corresponding limitation set forth in the asserted claim. *Pozen Inc. v. Par Pharm., Inc.*, 696 F.3d 1151, 1167 (Fed. Cir. 2012).

iii. Indirect Infringement

17. A defendant can indirectly infringe a method claim by inducing infringement or by contributing to its infringement. 35 U.S.C. §§ 271(b) and (c). To prove inducement of a method claim, Plaintiffs must prove by a preponderance of the evidence that Defendants (1) have sold, or will sell upon approval of their respective ANDAs, the accused generic tablets with knowledge of the patents in suit, (2) have knowingly induced or will knowingly induce others to perform all the claimed method steps, and (3) have specifically intended or will specifically intend to encourage them to infringe. *Limelight Networks, Inc. v. Akamai Techs, Inc.*, 134 S. Ct. 2111, 2116-17 (2014); *Minnesota Min. & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1304-05 (Fed. Cir. 2002).* Specific intent can be inferred from circumstantial evidence. *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006). In the ANDA context, if the defendant's proposed label instructs users to perform the patented method, the proposed label may provide evidence of the defendant's affirmative intent to induce infringement. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010)

18. To prove contributory infringement, Plaintiffs must prove by a preponderance of the evidence that (1) Defendants' generic tablets are being or will be used to commit acts of direct infringement, (2) the generic tablets constitute a material part of the invention, (3) Defendants know their products are especially made or adapted for use in the patented method, and (4) the generic tablets are not staple articles or commodities of commerce suitable for a substantial noninfringing use. 35 U.S.C. § 271(c); *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 850-51 (Fed. Cir. 2010) *aff'd*, 131 S. Ct. 2238 (2011).

B. Invalidity Defenses

i. Burden of Proof

19. The patents-in-suit are presumed valid. 35 U.S.C. § 282. Defendants have the burden of proving invalidity by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242-43 (2011). The USPTO's decisions that the patents met the statutory requirements for patentability, although not binding on this Court, are entitled to deference. *Id.*; *American Hoist & Derrick Co.* v. *Sowa & Sons*, 725 F.2d 1350, 1359 (Fed. Cir. 1984); *Sanofi-Synthelabo v. Apotex, Inc.*, 488 F. Supp. 2d 317, 330 (S.D.N.Y. 2006).

ii. Patent-Eligible Subject Matter

20. To prove that the subject matter of a patent claim is not patent-eligible, Defendants must prove by clear and convincing evidence that (1) the claim reads on a law of nature or natural phenomenon, and (2) the combination of elements in the claim are not sufficient "to ensure that the patent in practice amounts to significantly more than a patent upon [the law of nature or natural phenomenon] itself." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354-55 (2014).

iii. Anticipation

21. In order to establish anticipation, Defendants have the burden of proving by clear and convincing evidence that every element of the asserted claims is expressly or inherently disclosed in a single prior art reference. *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003).

22. The absence of any limitation defeats an argument of anticipation. *In re Skvorecz*, 580 F.3d 1262, 1266 (Fed. Cir. 2009); *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1554 (Fed. Cir. 1995). Further, "it is not enough that the prior art reference discloses part of the claimed invention, which an ordinary artisan might supplement to make the

whole, or that it includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention." *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008). Instead, the prior art "must clearly and unequivocally" disclose the claimed invention as it is arranged in the claims "without *any* need for picking, choosing, and combining various disclosures." *In re Arkley*, 455 F.2d 586, 587 (C.C.P.A. 1972) (emphasis in original) (reversing Board's finding of anticipation where Board combined the disclosures of two examples and other teachings in the prior art patent); *Net MoneyIN*, 545 F.3d at 1370-71 (finding that combining two "links" from different internet payment protocols was insufficient to establish anticipation).

23. Although a prior-art reference may be anticipatory absent an explicit disclosure of a feature of the claimed invention, that missing feature must be necessarily and inevitably present, or inherent, in the single anticipating reference. *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 1000 (Fed. Cir. 2006) ("[A]nticipation by inherent disclosure is appropriate only when the reference discloses prior art that must necessarily include the unstated limitation."); *accord Cont'l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991); *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003).

24. In order to show anticipation, by allegedly reproducing a prior art example, Defendants must prove that they have, in fact, faithfully replicated the teaching of the prior art. *See Glaxo, Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047-48 (Fed. Cir. 1995). Tests that vary the teaching of the prior art are not probative of what a reference inherently discloses. *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH.*, 98 F. Supp. 2d 362, 387-91 (S.D.N.Y. 2000); *see Glaxo, Inc. v. Novopharm Ltd.*, 830 F. Supp. 871, 877 (E.D.N.C. 1993) *aff'd*, 52 F.3d 1043 (Fed. Cir. 1995).

25. To incorporate material from outside the four corners of the document itself, a patent "must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2002); *SkinMedica, Inc. v. Histogen Inc.*, No. 09-CV-122JLS, 2011 WL 2066619, at *7 (N.D. Cal. 2011) (applying the above standard and stating that "a general reference to a voluminous publication is not sufficient to incorporate by reference a specific portion of a host document").

26. Because a finding of anticipation under § 102 deprives the fact finder of the ability to consider objective evidence relating to the actual contribution the inventor has made and the real-world importance of the claimed invention, the anticipation inquiry is necessarily strict. *In re Arkley*, 455 F.2d at 587 (noting that an anticipation holding excused the Board from considering the "extensive objective evidence" regarding nonobviousness). Anticipation deals with the narrow and rare situation where the very thing sought to be patented is already in the public domain. Indeed, "[c]ases involving novelty, with its strict identity requirement, are quite rare." *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1297 (Fed. Cir. 2002). All other situations are left to the standard of obviousness set forth in 35 U.S.C. § 103, where objective evidence "may often be the most probative and cogent evidence in the record" of the true value of an invention. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983).

iv. On-Sale Bar

27. To prove that the on-sale bar applies, Defendants must prove by clear and convincing evidence that, more than one year before the patent application was filed, "(1) the product was the subject of a commercial offer for sale and (2) the invention was ready for patenting." *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67 (1998). To establish that the product was the subject of a commercial offer for sale, Defendants must prove that (a) the product sold "fully

anticipated the claimed invention or would have rendered the claimed invention obvious by its addition to the prior art[,]" *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1352 (Fed. Cir. 2002), (b) someone made an offer that "was a *definite* sale or offer to sell," *Grp. One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1045 (Fed. Cir. 2001) (emphasis added), (c) the offer was an offer for "sale" in the sense that it was "a contract between parties to give and to pass rights of property for consideration[,]" not a contract for services, *Trading Technologies Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1361 (Fed. Cir. 2010), and (d) the sale was commercial, rather than primarily for the purpose of experimentation, *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 996 (Fed. Cir. 2007). To establish that the invention was ready for patenting, Defendants must prove that the inventors knew the invention would work for its intended purpose without further development or verification. *In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1375 (Fed. Cir. 2008); *Space Sys./Loral, Inc. v. Lockheed Martin Corp.*, 271 F.3d 1076, 1080 (Fed. Cir. 2001).

v. Obviousness

28. To prove that the asserted claims are obvious, Defendants must prove by clear and convincing evidence that the differences between the claimed subject matter and the prior art are such that the invention would have been obvious to a hypothetical person having ordinary skill in the art at the time of invention. 35 U.S.C. § 103; *Microsoft*, 131 S. Ct. at 2242. To determine obviousness, the Court must consider "(i) the scope and content of the prior art; (ii) the differences between the prior art and the claims at issue; (iii) the level of ordinary skill in the pertinent art; and (iv) objective or secondary considerations, such as a long-felt but unresolved need for the claimed invention, the failure of others, unexpected results . . . whether the invention has enjoyed commercial success [and copying]." *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998). Even if the prior art discloses all the

elements of a claim, the claim is only obvious if a person of ordinary skill in the art would be motivated to combine the elements and would have a reasonable expectation that the combination would result in the claimed invention. *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1364 (Fed. Cir. 2011); *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009). "[W]hen the prior art as a whole teaches away from combining certain known elements" by discouraging a person of ordinary skill in the art from following the path set out in the prior art or by leading the skilled artisan in a direction divergent from the path that was taken by the inventors of the claimed invention, "a successful means of combining [the known elements] is more likely to be nonobvious." *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007); *Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009).

29. Hindsight must be avoided in the obviousness analysis. *KSR*, 550 U.S. at 421. "[T]he great challenge of the obviousness judgment is proceeding without any hint of hindsight." *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1375 (Fed. Cir. 2011). When fact-finders fall prey to a hindsight-driven obviousness analysis, they often find motivation and a reasonable expectation of success where none existed at the time of the invention. *See, e.g.*, *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364-65 (Fed. Cir. 2008); *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (Fed. Cir. 1998). That which was unknown cannot have been obvious. *In re Newell*, 891 F.2d 899, 901-02 (Fed. Cir. 1989); *see also In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993) ("[s]uch a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection."). The claimed invention must be viewed "in the state of the art that existed at the time the invention was made." *Sensonics Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1570 (Fed. Cir. 1996).

30. Objective evidence of non-obviousness must always be considered before reaching any legal conclusion of obviousness. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1555 (Fed. Cir. 1983). Only after all evidence of non-obviousness has been considered can a conclusion on obviousness be reached. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1075-80 (Fed. Cir. 2012). This evidence "often serve[s] as insurance against the insidious attraction of the siren hindsight when confronted with the difficult task of evaluating the prior art." *W.L. Gore*, 721 F.2d at 1553.

vi. Written Description

31. To prove that claims lack written description support under 35 U.S.C. § 112, Defendants must prove by clear and convincing evidence that the specification would not convey to a person of ordinary skill in the art that the inventors were in possession of the invention when they filed the patent application. *Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1351 (Fed. Cir. 2011). Neither an actual reduction to practice nor examples covering the full scope of the claim language are necessary to support the adequacy of written description. *Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006). "[I]t is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention . . . ." *Id.* (quoting *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005)).

32. Under the written description requirement, the patentee must objectively demonstrate that he was actually in possession of the claimed subject matter at the time of the invention. *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1349 (Fed. Cir. 2010). The test for sufficiency of written description requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. *Id.* The written description requirement does not require the applicant to describe exactly the subject matter

claimed, as long as the description clearly allows persons of ordinary skill in the art to recognize that he or she invented what is claimed. *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1321 (Fed. Cir. 2003) (citing *Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000)).

vii. Enablement

33. To prove that the claims are not enabled under 35 U.S.C. § 112, Defendants must show by clear and convincing evidence that a person of ordinary skill in the art, using the knowledge available to him and the disclosure in the patent, could not make and use the claimed invention without undue experimentation. *Cephalon, Inc. v. Watson Pharm.*, 707 F.3d 1330, 1336 (Fed. Cir. 2013). The specification may satisfy the enablement requirement even if a person of ordinary skill in the art would need to engage in a considerable amount of experimentation, so long as the experimentation is merely routine or the specification provides a reasonable amount of guidance about the direction in which the experimentation should proceed to practice the invention. *PPG Indus. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996). The specification does not need to "contain examples explicitly covering the full scope of the claim language" in order to be enabling. *LizardTech*, 424 F.3d at 1345. "The enablement requirement is met if the description enables any mode of making and using the invention." *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1071 (Fed. Cir. 2005) (citing *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998)). The Court may consider the following factors when determining whether undue experimentation would be required: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the

art, and (8) the breadth of the claims." *Cephalon*, 707 F.3d at 1336 (quoting *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)).

viii. Definiteness

34. To prove that a claim is indefinite under 35 U.S.C. § 112, Defendants must show by clear and convincing evidence that, "when viewed in the light of the specification and prosecution history, [the claim does not] inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). While clarity is required, it is also recognized that absolute precision is unattainable. *Id.* at 2129. Thus, the degree of certainty required is no more than is reasonable, given the subject-matter. *Id.* Definiteness is a question of law evaluated from the perspective of someone skilled in the relevant art at the time the patent was filed. *Id.* at 2128; *DDR Holdings, LLC v. Hotels.com*, L.P., 773 F.3d 1245, 1260 (Fed. Cir. 2014).

35. Optional limitations cannot serve as the basis for an invalidity determination. *In re Johnston*, 435 F.3d 1381, 1384 (Fed. Cir. 2006). Thus, optional limitations are not relevant to the indefiniteness inquiry.

C. Unclean Hands Defense

36. To prove unclean hands, a defendant must demonstrate that the plaintiff engaged in "inequitable conduct or bad faith where the misconduct has a material relation to the equitable relief that the plaintiff seeks." *Stokely-Van Camp, Inc. v. Coca-Cola Co.*, 646 F. Supp. 2d 510, 533 (S.D.N.Y. 2009) (citations omitted). The alleged misconduct must be "directly related to the subject matter in the litigation." *PenneCom B. V. v. Merrill Lynch & Co., Inc.*, 372 F.3d 488, 493 (2d Cir. 2004) (internal quotations omitted). In addition, the defendant must prove injury as a result of the inequitable conduct. *Obabueki v. Int'l Bus. Machines Corp.*, 145 F. Supp. 2d 371, 401 (S.D.N.Y. 2001).

IV. THE ENDO PATENTS (THE ’122 AND ’216 PATENTS)

A. Defendants Directly and Indirectly Infringe the Endo Patents

37. Endo owns the ’122 and ’216 patents and asserts claims against all Defendants with respect to those patents. Each of Defendants’ generic tablets directly and indirectly infringe one or more of the asserted patent claims—claims 2, 3, 19, and 20 of the ’122 patent, and claims 1, 22, 40, 42, 50, 54, 57, 62, 64, 71, 73, 74, 78, 79, 80, and 82 of the ’216 patent.

B. All Defendants Directly Infringe the Endo Patents’ Product Claims

38. In an ANDA case like this, infringement can be proven by Defendants’ ANDA submissions and other regulatory filings. *Sunovion*, 731 F.3d at 1280 (holding that defendant’s ANDA specification infringed claims as a matter of law). Here, the package inserts, product labels, biowaiver requests, manufacturing information, dissolution testing data, and clinical study data that Defendants submitted to the FDA show that Defendants’ generic tablets meet each and every limitation of the asserted claims. The evidence at trial—including Defendants’ ANDAs, testimony from Plaintiffs’ fact witnesses, cross-examination of Defendants’ witnesses, and the testimony of Endo’s scientific experts (Dr. Fassihi, Dr. Ross, and Dr. Ogenstad)—will show that each Defendant will infringe the asserted claims identified in the chart below.

CLAIMS ASSERTED AGAINST EACH DEFENDANT		
DEFENDANT	’122 PATENT CLAIMS	’216 PATENT CLAIMS
Actavis CRF (13-cv-436)	[redacted]	
Amneal CRF (12-cv-8115)		
ThoRx CRF (12-cv-8317)		

CLAIMS ASSERTED AGAINST EACH DEFENDANT		
DEFENDANT	**'122 PATENT CLAIMS**	**'216 PATENT CLAIMS**
Impax CRF (13-cv-435)	[redacted]	[redacted]
Sandoz CRF (12-cv-8318)		
Teva CRF (12-cv-8060)		
Ranbaxy CRF (13-cv-8597)		
Actavis Non CRF (12-cv-8985)		
Roxane Non CRF (13-cv-3288)		
Ranbaxy Non CRF (13-cv-4343)		
Par Non CRF (13-cv-3284)		

C. Defendants' Non-Infringement Arguments

39. During the Final Pretrial Conference conducted by the Court on January 22-23, 2015, the parties and the Court identified three disputed infringement issues for trial:

(1) Whether the results of dissolution testing using 900 mL of dissolution fluid [redacted] are comparable to the results that would be obtained using 500 mL of dissolution fluid (as is set forth in the dissolution test procedure specified in the patent claims) (*see* 1/22/15 Tr., at 52:1-55:18);

(2) Whether the data described in the proposed package inserts that Defendants submitted to the FDA, and the clinical data provided to the FDA regarding Defendants' generic tablets and Opana® ER, prove by a preponderance of the evidence that Defendants' accused tablets satisfy the limitations recited in some

of the asserted claims relating to differences in the extent that the drug is absorbed into the bloodstream of patients under "fed" versus "fasted" conditions (*see* 1/22/15 Tr. at 60:21-67:19); and

(3) Whether selling tablets with package inserts and container labels that direct patients to infringe the claimed methods for treating patients for pain is legally sufficient to prove that Defendants have and/or will induce infringement under 35 U.S.C. § 271(b) (*see* 1/22/15 Tr. at72:4-89:12).

40. Other than these three issues, Defendants do not dispute any other aspects of Endo's infringement proofs with respect to the '122 and '216 patents. For the reasons specified in detail in Dr. Fassihi and Dr. Ogenstad's expert reports, consistent with which they will testify at trial, none of Defendant's non-infringement defenses are sufficient to overcome Endo's proofs of infringement.

D. All Defendants Indirectly Infringe the Endo Patents' Method Claims

41. The evidence at trial—including Defendants' ANDAs, testimony from Plaintiffs' fact witnesses, cross-examination of Defendants' witnesses, and Dr. Fassihi and Dr. Ogenstad's expert testimony—will show that the proposed package inserts and labels that Defendants submitted to the FDA and have included or will include with the sale of their generic tablets establish specific intent to induce patients to infringe the method claims. *See, e.g., AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010) ("[A] proposed label may provide evidence of [a defendant's] affirmative intent to induce infringement" if "the proposed label instructs users to perform the patented method."). Defendants' ANDAs and regulatory submissions prove that Defendants' generic tablets are specially adapted, material parts of the claimed methods of treatment that have no substantial non-infringing uses. All Defendants are therefore liable for inducement and contributory infringement.

E. The Endo Patents Are Valid

42. Defendants raise invalidity defenses under 35 U.S.C. §§ 101 (patent-eligible subject matter), 102(b) (on-sale bar), 103 (obviousness), and 112 (written description, enablement, and definiteness). As issued patents, the Endo patents are presumed to be valid. 35 U.S.C. § 282; *Microsoft Corp. v. i4i Limited Partnership*, 131 S. Ct. 2238, 2241 (2011). To overcome that presumption, Defendants require clear and convincing evidence of invalidity. *Microsoft*, 131 S. Ct. at 2242.

43. The evidence at trial—including the testimony of Plaintiffs' fact witnesses, the cross-examination of Defendants' witnesses, and the opinions of Endo's expert witnesses (Drs. Stavchansky, Fassihi, Ross, Bell, and Gergel)—will show that Defendants fail to meet their burden of proving invalidity by clear and convincing evidence.

i. Patent-Eligible Subject Matter

44. Defendants Teva, Impax, ThoRx, Sandoz, and Actavis argue that claim [redacted] of the '122 patent and asserted claims [redacted] of the '216 patent are invalid because they are directed to inherent characteristics of oxymorphone, which are allegedly patent-ineligible natural phenomena.

45. The asserted claims are directed to actual tablets and the use of those tablets to treat actual patients for pain. Thus, they are not directed to abstract ideas or natural phenomena, and Defendants' arguments, if actually presented at trial, are frivolous.

46. Defendants' arguments also fail because the claimed characteristics are not inherent to oxymorphone, such that there is no reason to believe that the claims are directed to unpatentable natural phenomena. Moreover, Defendants' experts' fail to apply the correct legal standard by focusing on a subset of limitations without considering whether additional elements in the claims individually or in combination prevent the claims from patenting a natural

phenomenon itself. Even if the alleged inherent limitations are deemed to be natural phenomena, taking into consideration the additional claim limitations, the asserted claims amount to significantly more than claims to natural phenomena themselves. Therefore, Endo's patent claims are not invalid under 35 U.S.C. § 101 for lack of patent-eligible subject matter.

ii. On-Sale Bar

47. All Defendants argue that the Endo patents are invalid under the on-sale bar, 35 U.S.C. § 102(b).

48. The evidence at trial will show that Defendants cannot meet their burden of proof. [redacted] Finally, the invention was not ready for patenting because the inventors did not know that the invention would work for its intended purpose until after the critical date, when they received final study reports for steady-state pharmacokinetic testing and clinical efficacy trials.

iii. Obviousness

49. All Defendants argue that the Endo patents are invalid for obviousness under 35 U.S.C. § 103.

50. Defendants cannot meet their burden of proving obviousness by clear and convincing evidence. An immediate release oral form of oxymorphone had been sold in the 1960s, but that product was withdrawn from the market in the early 1970s, such that no oral oxymorphone product had been available for about 30 years at the time of the claimed invention, and very little was known about the characteristics of orally administered oxymorphone. Making

an extended release oxymorphone tablet was not on anyone's radar screen at the time Endo decided to pursue it, and developing a successful extended release oxymorphone tablet that provides 12-hours of pain relief was far from obvious at the time. Now that Endo has invested huge resources into the research and development of its patented and highly successful Opana® ER tablets, nine generic manufacturers have come along and copied Endo's technology, claiming that it was obvious all along. That hindsight world view is impermissible.

51. With respect to Defendants' proofs, there are significant differences between the prior art and the claimed inventions. In particular, the prior art did not teach or suggest the specific dissolution characteristics claimed in the '122 and '216 patents for controlled release oxymorphone formulations that provide analgesia (pain relief) for at least twelve hours. Additionally, in view of the unique properties of oxymorphone—most notably its exceptionally low oral bioavailability—the prior art taught away from developing a controlled release formulation of oxymorphone. Further, it is because of these properties of oxymorphone that an ordinarily skilled artisan would not have reasonably expected that a controlled release oxymorphone formulation would be analgesically effective for at least twelve hours or that the prior art dissolution profiles, which yield desired *in vivo* effects for controlled release formulations of other drugs, would result in the claimed pharmacokinetic and pharmacodynamic characteristics of controlled release oxymorphone.

52. Moreover, "relevant objective considerations, when considered as part of the totality of the evidence, [may] support a nonobviousness finding." *In re Cyclobenzaprine*, 676 F.3d 1063, 1083 (Fed. Cir. 2012) (holding that claims to therapeutically effective extended release drug were nonobvious in light of long-felt need, failure of others, and absence of a known pharmacokinetic/pharmacodynamic relationship). Here, several secondary considerations—

including at least the facts that (1) the claimed controlled release oxymorphone compositions resulted in unexpected bioavailability and efficacy, (2) Opana® ER, which embodies the asserted claims, enjoyed commercial success, (3) Opana® ER resolved a long-felt need for a new controlled release opioid, and (4) Defendants copied Opana® ER—further demonstrate that the asserted claims are not obvious.

iv. Written Description

53. Defendants Teva, Impax, ThoRx, Sandoz, Actavis, and Amneal argue that the Endo patents are invalid for failure to provide an adequate written description of the claimed inventions under 35 U.S.C. § 112.

54. The Endo patents adequately describe the claimed inventions. Contrary to Defendants' assertion, ordinarily skilled artisans would have understood from the specification, in light of the existing knowledge in the field, the extent and content of the prior art, the maturity of the field of the invention, and the degree of predictability of various aspects of the invention, that the inventors possessed the inventions as claimed. Indeed, there is express written support in the specification for all asserted claim limitations. The asserted claims are drawn specifically to controlled release oxymorphone formulations. Although the patent specification need not disclose any examples to satisfy the written description requirement, the specification of the '122 and '216 patents contains multiple working examples of the claimed controlled release oxymorphone inventions. Moreover, the specification adequately describes the dissolution testing conditions, adequately supports the claimed dissolution ranges, and provides adequate structural limitations for the claimed dosage forms. Further, the specification provides adequate written support for the analgesic effectiveness and associated 12-hour dosing intervals for the full scope of the claimed dissolution ranges. An ordinarily skilled artisan would understand that the specification demonstrates that the disclosed formulations would achieve pain relief for

twelve to twenty-four hours. The written description also adequately describes the claimed pharmacokinetic limitations. Defendants contradict themselves with respect to the claimed pharmacokinetic properties, arguing in the obviousness context that those properties are inherent and necessarily present, but arguing in the written description context that the specification does not adequately describe those properties. Additional examples using a variety of controlled release delivery systems were unnecessary because controlled release delivery technology was mature at the time of invention, and an ordinarily skilled artisan would know how to use different systems to achieve the claimed dissolution rates. Ultimately, Defendants' arguments fail to satisfy the burden of proving inadequate written description by clear and convincing evidence.

v. Enablement

55. All Defendants except Par argue that the Endo patents are invalid because they do not enable others to make and use the claimed invention, as is required under 35 U.S.C. § 112.

56. Here, with the benefit of Endo's patented technology as a guide, at least nine separate generic manufacturers have been able to successfully make twelve different generic oxymorphone tablet formulations that each provide for twelve hours of pain relief.

57. Defendants raise many of the same arguments in the enablement context as they raise in the written description context. Their arguments fail for the same reasons. Defendants ignore the state of the art with respect to controlled release technology. Moreover, Defendants adopt contradictory positions, arguing in the enablement context that *in vivo* testing would be necessary to enable the claims, but arguing in the obviousness context that one would be able to predict *in vivo* results based on *in vitro* dissolution testing. In light of the fact that each Defendant has been able to make a therapeutically effective controlled release oxymorphone formulation that satisfies the claim limitations, Defendants' enablement arguments are difficult

to understand. The patent examiner thoroughly considered and resolved issues of enablement during prosecution. Accordingly Defendants fail to provide clear and convincing evidence that the Endo patents are not enabled.

vi. Definiteness

58. Defendants Teva, Impax, ThoRx , Sandoz, and Actavis argue that claim [redacted] of the '122 patent and claims [redacted] patent are invalid for indefiniteness under 35 U.S.C. § 112.

59. Defendants' indefiniteness arguments fail to convince even their own experts. Defendants argue that the pharmacokinetic limitations are indefinite because it is unclear what a "peak" is and how to measure "detectable blood plasma levels." But even Defendants' expert, Dr. Banakar, admits that "peak" has an ordinary meaning that a skilled artisan would understand. And the specification explains that pharmacokinetic properties are intended to be measured through a study conducted according to standard FDA procedures, so a skilled artisan would know how to measure "detectable blood plasma levels." In light of the ordinary meaning of the claim terms and the guidance that the specification provides, Defendants cannot prove by clear and convincing evidence that the claims are indefinite.

F. Roxane's Unclean Hands Defense Does Not Bar Injunctive Relief

60. Roxane also intends to present an "unclean hands" defense against Endo, which it described for the first time at the January 23, 2015 Final Pretrial Conference. The Federal Circuit and this Court have already rejected the bases for this defense as a matter of law, and the evidence Roxane proffers is legally insufficient to prove injury. Endo has therefore moved to strike the defense.[6] Roxane's arguments in support of its unclean hands defense are insufficient

[6] 13-cv-3288-TPG Dkt. Nos. 110 and 111 (filed Feb. 26, 2015).

as a matter of law, as this Court and the Federal Circuit have already ruled. Therefore, Roxane's unclean hands defense does not preclude injunctive relief.

V. THE '482 PATENT

61. Among the claims originally set forth in its complaints, Endo asserted that each of the Defendants infringed claims 1 – 4 of the '482 patent. As Endo had previously advised the Court, however, there were parallel proceedings instituted by the Patent & Trademark Office ("PTO") in connection with that patent. Those proceedings have now been concluded, and the PTO has entered judgment against Endo, cancelling all of those asserted claims of the '482 patent. Accordingly, all of the claims of the '482 patent that Endo had asserted against any defendant in these matters have now been cancelled, and as a result, there are no triable issues with respect to the '482 patent. The Court has dismissed the Counts relating to the '482 patent in Case Nos. 12-cv-8115, 13-cv-436, 12-cv-8985, 13-cv-8597, 13-cv-4343, and 12-cv-8060 by the parties' stipulations. The Court further approved the dismissal of the '482 patent at the hearing on March 3, 2015.

VI. REQUEST FOR RELIEF

62. Defendants' ANDA submissions and regulatory filings prove that the accused tablets practice each and every limitation of the asserted claims of the '122 and '216 patents. Defendants fail to satisfy their burden of proving invalidity by clear and convincing evidence. Plaintiff Endo therefore seeks the relief described in its complaints, including but not limited to (1) judgments that Defendants infringe the asserted patents, (2) a declaration that the asserted patents are valid and enforceable, (3) an order that Defendants' ANDAs may not be approved under the Food, Drug and Cosmetic Act until after Plaintiff's patents have expired, including any extensions, and (4) a permanent injunction barring Defendants from making or selling the accused generic tablets prior to expiration of the Plaintiff's patents, including any extensions

thereto. Plaintiff Endo also seeks an award of its costs and fees pursuant to 35 U.S.C. § 285 and Federal Rule of Civil Procedure 54(d)(1).

Respectfully submitted,

Dated: March 11, 2015

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CERTIFICATE OF SERVICE

I hereby certify that on March 11, 2015, I caused to be served the foregoing **PLAINTIFF'S STATEMENT OF THE ELEMENTS AND FACTS CONCERNING ITS CLAIMS FOR PATENT INFRINGEMENT** on counsel listed below via email.

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Dated: March 11, 2015

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